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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/519,042	07/13/2005	Sushil Kumar Sharma	ON/4-32563A	7042

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EXAMINER	
HEARD, THOMAS SWEENEY	
ART UNIT	PAPER NUMBER
1654	
MAIL DATE	DELIVERY MODE
02/14/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/519,042	SHARMA ET AL.	
	Examiner	Art Unit	
	THOMAS S. HEARD	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 December 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *15-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *15-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/20/2007 has been entered.

The Applicants Amendments to the claims received on 12/20/20007 is acknowledged. The text of those sections of Title 35 U.S. Code not included in the action can be found in the prior office action. Rejections or objections not addressed in this office action with respect to the previous office action mailed 3/30/2007 are hereby withdrawn.

Claim(s) 15-24 are pending. Applicants have not amended any claims. Claims 1-10 are hereby examined on the merits.

For the record of prosecution, Applicants have elected the following compound corresponding to Compound 1 in Example 1 in the specification:

R_1, R_6 and R_7 are each H;

R_2 and R_3 are each methyl;

R_4 is $-CH(CH_3)_2$;

X is N;

R_5 is $-CH_2CH_2$-Phenyl;

R_8 is $-NR_{12}R_{13}$ where R_{12} is H and R_{13} is C(O)-CH_2-cyclohexyl, which is also the same species found in 11/203,370 and also elected. Applicant's elected species has been found free of the prior art.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 15-24 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for binding of the example compounds (Examples 1-29 disclosed in the specification on pages 17-22) to the BIR3 peptide binding pocket in the FRET assay described on page 21 of the specification, does not reasonably provide enablement for treating a proliferative disease in a mammal or human. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The factors to be considered in determining whether a disclosure meets the enablement requirements of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir., 1988). The court in Wands states, "Enablement is not precluded by the necessity for some experimentation, such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue', not 'experimentation'" (Wands, 8

USPQ2sd 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations" (Wands, 8 USPQ2d 1404). Among these factors are: (1) the nature of the invention; (2) the breadth of the claims; (3) the state of the prior art; (4) the relative skill of those in the art; (5) the predictability or unpredictability of the art; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

While all of these factors are considered, a sufficient amount for a *prima facie* case is discussed below.

(1) The nature of the invention and (2) the breadth of the claims:

The claims are drawn to plurality of compounds thought to have anti-proliferative properties. Thus, the claims taken together with the specification imply treatment of a plurality of unrelated diseases encompassed under the term proliferative diseases, see abstract of Sporn MB, Harris ED Jr., "Proliferative Diseases, "Am J Med. 1981 Jun;70(6):1231-5 for examples of unrelated diseases that are covered under the term "proliferative."

(3) The state of the prior art:

Terui Y., et al, "NH2-terminal pentapeptide of endothelial interleukin 8 is responsible for the induction of apoptosis in leukemic cells and has an antitumor effect in vivo," Cancer Res. 1999 Nov 15;59(22):5651-5 discloses compounds of the instantly

claimed invention that do not have apoptotic activity nor anticancer activity, such as AVP and VLP, see Figure 1C and "*Deletion Analysis of the Active Site of NH2-Terminal Pentapeptide AVLPR*" section on page 5653. These compounds are readable upon Formula (I) where R_1, R_2, R_5-R_8 are H and R_3 is methyl or isopropyl and R_4 is isopropyl

(4) The relative skill of those in the art:

The relative skill of those in the art is high, usually at the level of graduate level training and MD for treatment regiments.

(5) The predictability or unpredictability of the art; (6) The amount of direction or guidance presented; (7) The presence or absence of working example; and (8) The quantity of experimentation necessary.

Since a core structure beyond a peptide backbone and its structural correlation to either a specific proliferative disease, or the plurality of diseases claimed, of the structure-function instantly claimed invention remains largely unsolved, and the means for correlating structure-function with a specific proliferative disease is highly unpredictable. The specification has provided a few examples that where shown to bind BIR3 via a FRET assay and those examples varied in IC_{50} over 6 orders of magnitude. However, the specification does not provide information on how these examples and their variance in IC_{50} correlate to inhibition and treatment of very broad proliferative diseases instantly claimed. Considering the state of the art as discussed by the Wands Factors supra and the high unpredictability and the lack of guidance provided in the specification, one of ordinary skill in the art would be burdened with undue experimentation to determine a core structure with activity toward a proliferative disease, and do so only with a FRET binding assay. It is the examiner's position that

one skilled in the art could not practice the invention commensurate in the scope of the claims without undue experimentation of trial and error synthesis and testing.

Applicant's arguments have been carefully considered but are not deemed persuasive to overcome the rejection as set forth supra. Applicants have argued:

It is well established that if in vitro tests correlate to a claimed method of invention, it constitutes a working example sufficient to provide enablement of the claims. See, e.g., MPEP 2164.02. This is particularly the case in instances where the state of the art recognizes such a correlation. In the present case, the compounds of the invention were shown to have activity in binding the BIR3 peptide binding pocket. Such activity has been shown to have a correlation to promoting apoptosis, which in turn has been shown lo be a therapeutic method of treating proliferative disease. See, e.g., Kipp et al, "Molecular Targeting of Inhibitor of Apoptosis Proteins Based on Small Molecule Mimics of Natural Binding Partners," Biochemistry, Vol. 41 (23), pp 7344-7349 (2002); and Arnt et al., "Synthetic Smac/DIABLO peptides enhance the effects of chemotherapeutic agents by binding XIAP and cIAP1 in Situ," Journal of Biological Chemistry, Vol. 277 (46), pp. 44236- 44243 (2002); both cited in the present IDS. There is therefore a clear corollary recognized in the art between the activity demonstrated in the specification and the resulting potential as a therapeutic against proliferative disease. The Examiner further states that, "proliferative disease encompass numerous and unrelated diseases, such as psoriasis and cancer. It is not understood how the administration of the compounds could embrace the treatment of such a large genus of diseases. It is for this that the rejection is maintained." See Office Action, page 3, first paragraph. This is not the proper standard of enablement. A method of treatment is not being claimed. Where a composition of matter is claimed, the claimed subject matter does not have to provide enablement for a medicament to treat all of the diseases encompassed within proliferative diseases. It is only necessary to determine whether one of skill in the art is enabled to make and use the entire scope of the claimed invention without undue experimentation. See MPEP 2164.08. It is only necessary that the specification enables the claimed composition to treat a proliferative disease. In the present case, the claims are directed to a composition of matter. There is no question as to whether the specification enables the claimed compound. Withdrawal and reconsideration of the rejection is required.

The Applicants are claiming a genus of diseases under the broad term proliferative. As stated supra, Sporn MB, Harris ED Jr., "Proliferative Diseases, "Am J Med. 1981 Jun;70(6):1231-5 provides numerous examples of unrelated diseases that are covered

under the term "proliferative," and are not connected to the SMAC protein that the compounds are purported to inhibit. The Sporn reference provided in presenting a case of non-enablement states that cancer, arteriosclerosis, rheumatoid arthritis, psoriasis, idiopathic pulmonary fibrosis, scleroderma, and cirrhosis of the liver are all proliferative diseases and are not connected via the smac protein. Cancer is a genus encompassing benign or aggressive terminal forms, leukemia, breast cancer, testicular, melanomas, etc, and these cancers are also not connected to smac protein inhibition. Arteriosclerosis is an autoimmune disease that is unrelated to cirrhosis of the liver that can be caused by excessive alcohol consumption. Applicants have a FRET assay that can determine the binding of a tripeptides instantly claimed but have not provided any other data that would enable the invention to treat proliferative diseases other than a correlation with smac binding. A FRET assay is not an in vitro or in vivo assay that would lend support that the binding would perform the desired downstream biological activity and that activity would be sufficient to treat or ameliorate the intended proliferative diseases. Note that Sporn' s article only samples a small population of proliferative diseases and many more diseases are embraced by the term proliferative. Further, regarding the Applicant's arguments that they are claiming a composition and not a method, the product must also be disclosed to be enabled to make and use the product. While the making of the product is not an issue, the specification only states that the product can be used for the treatment of proliferative diseases, including cancer (see page 1). The specification states that the pharmaceutical is used "for the treatment of proliferative diseases, including tumors, and other cancers. . ." (see page 9). Further,

on page 10, the specification states that the compound is administered for "inhibition of proliferation of malignant cancer cells, benign tumor cells or other proliferatie cells." Finally, the specification states that a "proliferative disease is mainly a tumor disesase." (see page 11 of the specification). Thus, taken as a whole, the specification only disclose one use for the products, i.e. treatment of proliferative diseases. It should also be noted that the certain claims recite the intended use of "treating a proliferative disease." Since the treatment of proliferative diseases is unpredictable, one would be burdened with undue experimentation using the claimed product for the treatment of proliferative diseases. Accordingly, Applicants have not taught how to and use the claimed product. Therefore, the enablement rejection is proper. It is the position of the prior art that proliferative disease(s) is so broad and unrelated, that it would be undue experimentation to test the compounds for all of the diseases claimed a proliferative. Regarding the Therefore, the rejection stands.

Claim 15-24 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The MPEP states that the purpose of the written description requirement is to ensure that the inventor had possession, as of the filing date of the application, of the specific subject matter later claimed by him. The courts have stated:

"To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997); In re Gostelli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, no that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966." Regents of the University of California v. Eli Lilly & Co., 43 USPQ2d 1398.

The MPEP lists factors that can be used to determine if sufficient evidence of possession has been furnished in the disclosure of the Application. These include "level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient." MPEP § 2163.

Further, for a broad generic claim, the specification must provide adequate written description to identify the genus of the claim. In Regents of the University of California v. Eli Lilly & Co. the court stated:
"A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." Fiers, 984 F.2d at 1171, 25 USPQ2d at 1606; In re Smythe, 480 F.2d 1376, 1383, 178 USPQ 279, 284985 (CCPA 1973) ("In other cases, particularly but not necessarily, chemical cases, where there is unpredictability in performance of certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus ...") Regents of the University of California v. Eli Lilly & Co., 43 USPQ2d 1398.

The MPEP further states that if a biomolecule is described only by a functional characteristic, without any disclosed correlation between function and structure of the sequence, it is "not sufficient characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence." MPEP 2163. The MPEP does state that for a generic claim the genus can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus. MPEP 2163. If the genus has a substantial variance, the disclosure must describe a sufficient variety of species to reflect the variation within that genus. See MPEP 2163. Although the MPEP does not define what constitute a sufficient number of

representative species, the courts have indicated what do not constitute a representative number of species to adequately describe a broad generic. In Gostelli, the courts determined that the disclosure of two chemical compounds within a subgenus did not describe that subgenus. In re Gostelli, 872, F.2d at 1012, 10 USPQ2d at 1618.

The factors considered in the Written Description requirement are (1) level of skill and knowledge in the art, (2) partial structure, (3) physical and/or chemical properties, (4) functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the (5) method of making the claimed invention.

In the instant case, the claims are drawn to complement activation peptides that are comprise a three amino acid backbone at minimum, and contain a substituent that facilitates transport of the molecule across a cell membrane.

(1) Level of skill and knowledge in the art:

The level of skill to practice the art of the instantly claimed invention is high with regard to chemical synthesis and assay design.

(2) Partial structure:

Modified tri- and tetra-peptides of natural and unnatural amino acids, whereby the functional moieties of R2, R3, and R4 broadly, for example, encompass compounds that do not share a common core structure.

(3) Physical and/or chemical properties:

Peptide inhibitors of SMAC.

(4) Functional characteristics:

Antagonist of SMAC binding protein that may induce apoptosis as determined by a FRET assay.

(5) Method of making the claimed invention:

Standard amino acid chemical synthesis with natural and modified amino acids.

As stated supra, the MPEP states that written description for a genus can be achieved by a representative number of species within a broad generic. It is unquestionable that claim 1 is a broad generic, with respect to all possible compounds encompassed by the claims. The possible structural variations are limitless to any class of peptide backbone extensively modified as claimed.

It must not be forgotten that the MPEP states that if a biomolecule is described only by a functional characteristic, without any disclosed correlation between function and structure of the sequence, it is "not sufficient characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence. "MPEP § 2163.

Here, though the claims may recite some functional characteristics, the claims lack written description because there is no disclosure of a correlation between function and structure of the compounds beyond compounds disclosed in the examples in the specification. There are a few example peptides and those examples do not demonstrate modifications that facilitate transport of the compounds across the membranes of cells or treat proliferative diseases. While having written description for compounds of Examples 1-29 identified in the specification tables and/or examples, the specification is void of any other peptides claimed in the Markush of Formula I or II that does not have a common core structure. There is insufficient description of chemical

modifications for membranes transport that would allow one of skill in the art to practice the invention as claimed. The examples in the specification are of limited scope, and do not present a representative sampling of the genus of Formula I and II which are a peptide backbone. The options of R2, R3, and R4 alone can make peptides of unrelated sequence that one of ordinary skill in the art would recognize from the backbone of Formula I or II. The description requirement of the patent statue requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See In re Wilder, 736, F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate.")

Further, 37 CFR 1.57(c) states that "Essential material" may be incorporated by reference, but only by way of an incorporation by reference to a U.S. patent or U.S. patent application publication, which patent or patent application publication does not itself incorporate such essential material by reference. "Essential material" is material that is necessary to:

(1) Provide a written description of the claimed invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and set forth the best mode contemplated by the inventor of carrying out the invention as required by the first paragraph of 35 U.S.C. 112;

(2) Describe the claimed invention in terms that particularly point out and distinctly claim the invention as required by the second paragraph of 35 U.S.C. 112; or

(3) Describe the structure, material, or acts that correspond to a claimed means or step for performing a specified function as required by the sixth paragraph of 35 U.S.C. 112.

For example, in the specification it is stated: "*substituents that facilitate transport of the molecule across a cell membrane are known to those of skill in the medicinal chemistry arts (see, for example, Gangewar S., Pauletti G. M.,Wang B., Siahaan T. J., StellaV. J., Borchardt R. T., Drug Discovery Today, vol. 2. p148-155 (1997) and Bundgaard H. and Moss J., Pharmaceutical Research, vol. 7, p 885 (1990)")* is deemed essential matter because in Claim 1 is claiming such substituents in functional language and without structures.

Accordingly, it is deemed that the specification fails to provide adequate written description for the genus of the claims and does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the entire scope of the claimed invention.

Applicant's arguments have been carefully considered but are not found to be persuasive to overcome the rejection as set forth supra. Applicants have argued:

The purpose of the written description requirement is not that an applicant need to describe exactly the subject matter claimed, but the description must clearly allow persons of ordinary skill in the art to recognize that-[he or she] invented what is claimed. See, e.g., In Re Gosteli, 872 F.2d 1008, 10 USPQ2d 1614 (Fed. Cir. 1989). In the present case, it is acknowledged by applicants on page 7 of the application that, "substituents that facilitate transport of the molecule across a cell membrane-are known

to those of skill in the medicinal chemistry art." The structure of the substituents is further recited in the first full paragraph on page 7 as including, "a C6-C3o alkyl which is saturated, monosaturated, polyunsaturated, including methylene-interrupted polyene, phenyl, phenyl which [is] substituted by one or two C1-C8 alkyl groups ....which is saturated, monosaturated, or polyunsaturated and straight or branched chain." The structural description in conjunction with the state of the art is therefore sufficient for written description requirements. Withdrawal of the rejection is respectfully requested. The Examiner has also rejected claims 1-10 as amended under 35 USC 112 as containing new matter. More particularly, the Examiner states that Applicants did not point out where in the specification the limitation of "wherein at least one of R1 and R2 is CH3" is found. Support for the amendment is found in the compounds of examples 1, 9, 10, 11, 12, 14, 15, 16-20, and 22-30. Withdrawal of the rejection is requested.

First, Applicants are restating some of the substituents that the peptide backbone may be substituted with and the claims already indicate this. This issue is understood. However, the substituents that facilitate transport of the molecule, as claimed in Claim 1, are considered essential matter and must be included in the specification to either a reference to a US Patent, or by directly incorporating the material from the journal references into the specification. Further, the definition of a substituent that would facilitate transport of a molecule has not been defined as a limiting definition. Applicants are merely reciting what it might be rather than what it actually is or what the substituents actually are. For example, Applicants state that "generally, such substituents are lipophilic substituents." This does not limit them to lipophilic and imply hydrophilic. Then, lipophilic substituents are listed as what they might be rather than what they are. Finally, a mere statement that one of ordinary skill in the art would know what constitutes as a substituents that facilitate transport of the molecule is not sufficient for overcoming the rejection. Therefore, the rejection as stated supra stands.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 15-24 stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 15-24 of copending Application No. 10/519, 042. Although the conflicting claims are not identical, they are not patentably distinct from each other because the compounds of the instantly claimed application are also claimed in '042, **as evidenced by the election of the same composition in both applications**.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicants have argued that they would consider filing a TD upon notification of allowable subject matter. The double patenting rejection cannot be withdrawn unless

the overlapping subject matter has been deleted between the two Applications.

Therefore, the rejection stands.

New Grounds of Rejection

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 15, 17, 18, and 20-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Soff et al, US Patent 6,576,609. Soff et al discloses the peptide SEQ ID NO:16, Ala Ala Pro Ala. This peptide is readable upon claims , 17, 18, and 20-24. Specifically, SEQ ID NO:16, Ala Ala Pro Ala, reads on R_1 and R_2 being H, R being $-CH_2Z$, and Z is H, R_4 is a C_1 straight chain alkyl (CH_3),, X is N, n is 1, R_7 and R_8 are H, R_5 is the amino acid alanine, whereby R_5 is a C_2 alkyl substituted with a methyl, a hydroxyl, and a oxygen (keto), and R_6 is H. Because this peptide is a Chromogenic Peptide Substrate for elastase, and was solvated in serum-free conditioned medium (SFCM), it is a pharmaceutical composition. Further, because the composition is readable upon the instant invention and claims 15, 17, 18, and 20-24, it must have the properties of treating proliferative diseases. Therefore, the invention as claimed is anticipated by the prior art.

Conclusion

No claims are allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP § 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 U.S.C. § 102 or 35 U.S.C. § 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is requested in response to this Office action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Thomas S. Heard** whose telephone number is **(571) 272-2064**. The examiner can normally be reached on 9:00 a.m. to 6:30 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on (571) 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Thomas S Heard/
Examiner, Art Unit 1654
Thomas S. Heard
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